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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,412	07/05/2001	Neal R. Cutler	CUTLER-06326	3297

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EXAMINER

JOYNES, ROBERT M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 11/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/899,412

Applicant(s)

CUTLER, NEAL R.

Examiner

Robert M. Joynes

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment filed on September 23, 2002.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-9 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Caruso (US 6043244). Caruso teaches a method treating migraines wherein dihydroergotamine is administered with an antimigraine-potentiating amount of an NMDA receptor antagonist (Col. 3, lines 14-58). Caruso contemplates all modes of administration (Col. 6, lines 3-67; Col. 7, lines 1-31). Specifically, sublingual administration is taught in the form of a tablet, drop or lozenge (Col. 6, lines 25-28). Sprays and pastes or gels are also taught by Caruso (Col. 6, lines 30-35, 63-65). The oral tablets further comprise additives such as calcium carbonate, calcium phosphate or kaolin (Col. 6, lines 18-24). Additional active agents may be added to the composition (Col. 8, lines 12-27). Caruso recites DHE and its pharmaceutically acceptable salts (Col. 3, lines 14-40). It is the position of the Examiner that any form of DHE, the salt or the base would be acceptable for the formulation of Caruso. Therefore, Caruso teaches all the limitations of the instant claims.

Claims 1, 2, 4-9 and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Plachetka (US 5872145). Plachetka teaches a method of treating

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migraines wherein an effective amount of a 5-HT agonist and NSAID are administered to a patient (Col. 13, Claim 1; Col. 3, lines 64-67). The 5-HT agonists include all types of 5-HT agonists, more specifically, 5-HT1, 5-HT1B and 5-HT1D agonists (Col. 8, lines 1-20). Dihydroergotamine mesylate is one such example (Col. 8, lines 1-20). The combination of active agents can be administered parenterally, enterally and topically and can be administered with appropriate carrier as well as other pharmaceutically acceptable excipients (Col. 12, line 31 – Col. 13, line 19). The dosage form can be in the form of quick-dissolve tablet (Col. 13, Claim 17). Therefore, Plachetka teaches all the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caruso or Plachetka. The teachings of Caruso and Plachetka are discussed above. Neither

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reference teaches that the DHE is in the base form. It is the position of the Examiner that any form of DHE would be effective in treating migraines. No criticality is seen in DHE being in the form of a base. Applicants have not shown any unexpected results from the base form.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use any form of DHE is a method of treating migraines.

One of ordinary skill in the art would have been motivated to do this to provide a method treating migraines that is effective and achieves the effect in a short amount of time to bring quick and direct relief to the host.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments with respect to claims 1-9 and 12-15 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Due to the new grounds for rejection, this action is deemed non-final.

Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joyner whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday through Friday 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
November 26, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600